EMS: Endless Medication Shortages ???





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Paul Davis, the chief of a rural ambulance squad in southern Ohio, was down to his last vial of morphine earlier this fall when a woman with a broken leg needed a ride to the hospital.

The trip was 30 minutes and the patient was in pain. But because of a nationwide shortage, his morphine supply had dwindled from 4 doses to just one, presenting Mr. Davis with a stark quandary. Should he treat the woman, who was clearly suffering? Or should he save it for a patient who might need it more?

Drug Shortages Causing Harm...

Looking for Drugs in all the Wrong Places Tell me why....

- Understand the causes of drug shortages in the U.S.
- Describe actions taken to prevent drug shortages from affecting the clinical management of patients.
- Name several drugs that have required drug shortage management strategies.
- Describe a variety of roles that clinicians of all specialties may be asked to take in drug shortage management.

Objectives

Change, Change, Change

Drug Shortages: *Scope of the Problem*



- Considerable attention in lay media
- Big enough problem to draw action from President, Congress and FDA
- Appears to be a growing issue
- Are shortages the new "norm"?



FDA Authorities are very limited

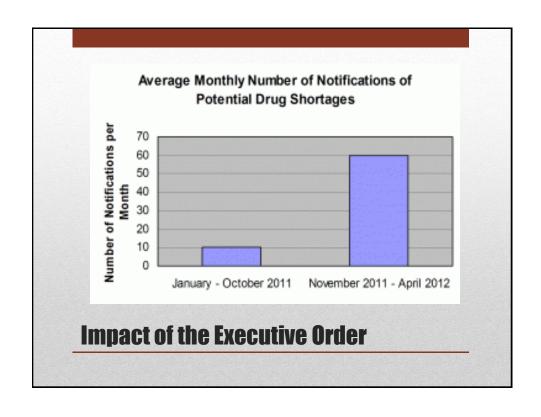
What we can require

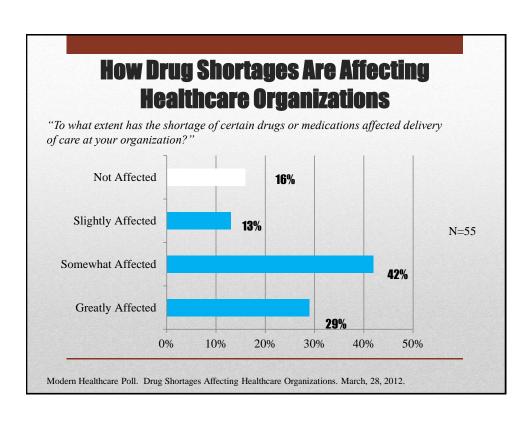
- Notification by manufacturers (new FDASIA requirement)
 - Supply disruptions, delays, discontinuations
 - · No penalty for not reporting
- Notification of manufacturing changes

What we can't require

- A company to make a drug or make more
- How much and to whom drug is sold or distributed

FDA Drug Shortages Program largely depends on notification by manufacturers and the public.

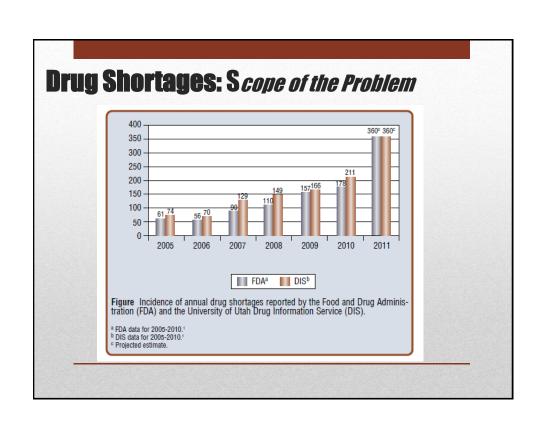


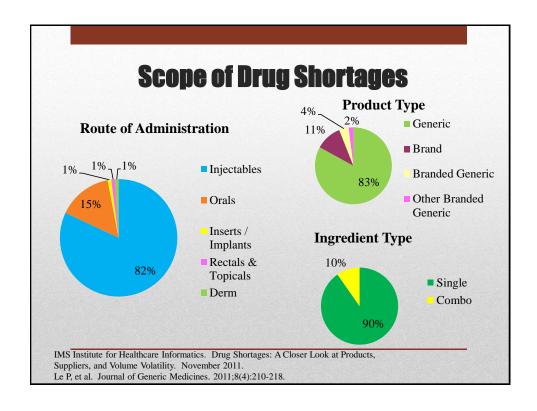


Drug Shortages: *Scope of the Problem*

- Primarily, but not only, injectables
- Impacts almost all health care environments
- Varies by area of country
- Varies by facility
- Varies over time as supply comes and goes
- Can be unexpected (eg recalls)







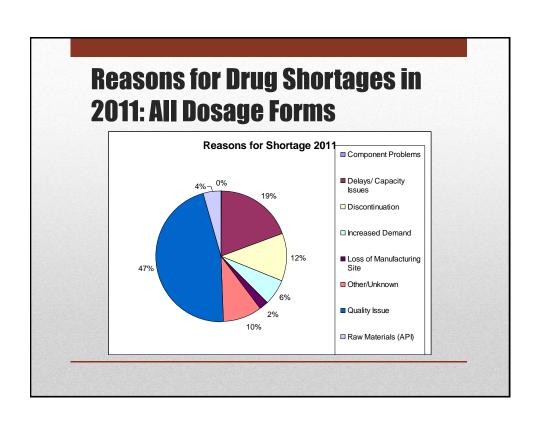
Drug Shortages: Causes

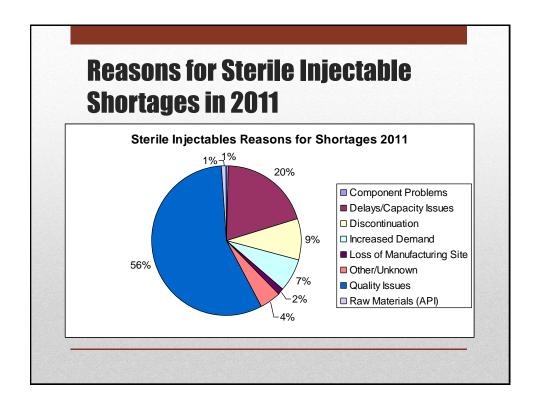
- Raw materials and Manufacturing issues
 - · Quality issues
 - Drug recalls
 - Foreign sources of materials and products
 - Economic:
 - · Low profit margins
 - · Fewer manufacturers
 - · Discontinuation for market reasons
 - Regulatory
 - · DEA and FDA
- "Secondary" shortages due to shift to alternative products



Drug Shortages: Causes

- Just in time inventory practices by wholesalers and institutions
 - Little supply "buffer"
- · Free market forces
 - Purchasing contracts
 - "Specialty" and "gray" market distributors
 - Compounding pharmacies





Examples of Recent Quality and Manufacturing Issues Involving Sterile Injectables - 1

- · Significant quality issues that have occurred
 - Sterility problems including bacterial and mold contamination
 - Particles of foreign matter (glass, metal and fibers) in vials
 - Crystallization of the active ingredient
 - Precipitate formation (due to reaction with raw materials or container/stopper with the drug)
 - · Newly identified impurities or degradants

Examples of Recent Quality and Manufacturing Issues Involving Sterile Injectables - 2

- Issues that are more easily able to be addressed
 - Errors in labeling or packaging
 - Slightly out of specification results that do not unfavorably alter benefit / risk
- Unforeseen/ Unanticipated issues
 - · Manufacturing equipment breakdown
 - Natural disasters or other events causing loss of manufacturing time and in some cases loss of inventory
 - · Fire at raw material or finished product manufacturing site
 - Japan earthquake caused several potential shortages
 - · Icelandic volcano caused transportation delays

Medication Shortages Affecting EMS Services 2012-2013

Potential Impact of Drug Shortages on EMS Services

- Therapy disruption or delay
- Stockpiling/hoarding occurrences
- Increased risk of adverse events
- Increased risk of medication errors
- Increased costs

Berger JE. AJPB. 2012 Jan/Feb; 4(1):10-11. ASHP. Am J Health-Syst Pharm. 2009;66:1399-1406. Le P et al. Journal of Generic Medicines. 2011;8(4):210-218.

Extended Expiration Dating

- Southern Nevada Health District
- Extended expiration dating on dopamine, morphine, magnesium, and etomidate for 6 months with an optional additional 6 months
- http://www.lasvegassun.com/news/2012/may/27/300-drugs-short-supply-southern-nevada-officials-w/

- *** ALERT ***
- Note Concentration
- Sodium Bicarbonate 8.4 %
- Substituted with 7.5 %

Concentration Changes

- Dextrose 50%
 - Substitution with Dextrose 10% solution
 - Supplied as 250ml(50gm), 500ml(100gm) or 1000ml(200gm) IV bags
 - Adult and Pediatric Dosing Recommendations
- Benzodiazepines and Fentanyl
 - Provide alternative dosing for midazolam and/or diazepam
 - Provide alternative dosing for morphine
 - Adult and Pediatric Dosing Recommendations

Emergency Protocols

	SHORTAGE/PACKAGE CHANGE LABEL Qty in box or Alternative Packaging
	FENTANYL (50mcg/ml)
	□ MORPHINE (10mg/ml) □ DIAZEPAM (10mg/2ml)
	□ MIDAZOLAM (5mg/1ml)
	Verified by Hospital
	aging Change fication
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DUE TO DRUG SHORTAGES This box has the following changes **ATROPINE Syringe – DECREASED from 3** >2 (May contain a kit) **DEXTROSE Syringe – May contain Vials EPINEPHRINE Syringe- DECREASED** from 7 > 5(May contain a kit) LIDOCAINE Syringe – DECREASED from 3 > 2(May contain vials instead of syringe) NALOXONE - Substitution of different volume same concentration **SODIUM BICARBONATE 8.4% -**Substitute with 50ml vial and 60ml syringe + 16g needle **CALCIUM CHLORIDE 10% - Substitute** with vial **Quantity Changes**

Drug Shortage Challenges

- Need for increased communication between stakeholders, including reasons for shortages and real-time updates on affected drugs
- Need to examine the gray market impact, including drastically increased pricing for shorted drugs
- Increased incidents of medication errors with the use of alternative therapies
- Need for standard alternative therapy guidelines
- Complex economic issues with shortages
- Need for a more stable supply chain
- · Call for a more standardized allocation process

FDA CDER Drug Shortage Public Workshop. September 26, 2011. Available at: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM275801.pdf

Drug Shortages: Questions?

